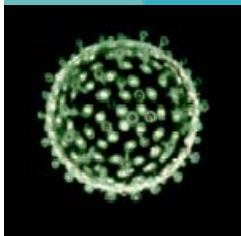




## Results from the Phambili (HVTN 503) study:

**A multicenter double-blind placebo-controlled phase IIB test-of-concept study to evaluate the safety and efficacy of the MRKad5 HIV-1 gag/pol/nef vaccine in HIV-1 uninfected South Africans.**

Gray G, Allen MA, Bekker L, Churchyard G, Mlisana K, Nchabeleng M, Moodie FZ, Metch B, Cassis-Ghavami F, Nicholson O, Kublin J and the NIAID HIV Vaccine Trials Network.





# Background

- Two phase IIB HIV vaccine trials using the Merck candidate (MRKad5 gag/pol/nef) were being conducted in two parts of the world
- The HVTN 502/STEP study was conducted in areas of the world where the predominant HIV sub-type was B, and the major risk of acquisition was through MSM, IDU & HS. This study enrolled 3000 participants.
- The HVTN 503/Phambili study was conducted in South Africa where the predominant HIV sub-type is C, and the major risk of acquisition was HS. This study was aborted in September 2007 after a STEP DSMB and only enrolled 801/3000 participants



# HVTN 503 - Primary Hypotheses

- **Primary Safety**

- The MRKAd5 HIV-1 gag/pol/nef vaccine will be safe and well tolerated in 18 to 35-year old HIV-1 seronegative adults.

- **Co-Primary Efficacy**

- **Infection endpoint**

- Subjects who receive the vaccine will have a lower likelihood of acquiring HIV-1 infection than those who receive placebo

**AND/OR**

- **Viral load endpoint**

- Among subjects who become HIV-1 infected, those who receive the vaccine will have a smaller average viral load set-point at ~ 3 months post seroconversion than those who receive placebo

## Methods

- Data was frozen 26 September 2008
- The endpoint analyses are based on a modified intent to treat (MITT) cohort
- Viral load analyses are limited to participants who have a minimum of 3 months of follow up post HIV diagnosis
- Viral load set-point is defined as the geometric mean of the values measured at visit 52.0 (~2 months post-diagnosis) and visit 53.0 (~3 months post diagnosis)

## Results

- Among 801 enrolled:
  - 216 (27%) received 1 vaccination
  - 529 (66%) received 2 vaccinations
  - 56 (7%) received 3 vaccinations
- Retention rate: 96% (14v,18p)
- 312 (70.7%) men were uncircumcised at baseline.
- 58 (18.6%) were circumcised during follow-up
- The overall incidence per 100 person-years of follow-up is 3.8% (95%CI=2.6-5.5) with 760 person years of follow-up



# Baseline Participant Characteristics

	Vaccine	Placebo	Total
Total Enrolled	400 (100.0%)	401 (100.0%)	801 (100.0%)
<b>Site</b>			
Soweto-PHRU	154 (38.5%)	154 (38.4%)	308 (38.5%)
Cape Town	84 (21.0%)	82 (20.4%)	166 (20.7%)
KOSH	110 (27.5%)	111 (27.7%)	221 (27.6%)
eThekwini	26 (6.5%)	27 (6.7%)	53 (6.6%)
Medunsa	26 (6.5%)	27 (6.7%)	53 (6.6%)
<b>Gender</b>			
Male	222 (55.5%)	219 (54.6%)	441 (55.1%)
Female	178 (44.5%)	182 (45.4%)	360 (44.9%)
<b>Ad5 NAb Titer</b>			
<= 18	75 (18.8%)	79 (19.7%)	154 (19.2%)
18-200	89 (22.3%)	113 (28.2%)	202 (25.2%)
201-1000	177 (44.3%)	157 (39.2%)	334 (41.7%)
> 1000	59 (14.8%)	52 (13.0%)	111 (13.9%)
<b>Age (years)</b>			
18 - 20	120 (30.0%)	119 (29.7%)	239 (29.8%)
21 - 25	166 (41.5%)	167 (41.6%)	333 (41.6%)
26 - 30	75 (18.8%)	71 (17.7%)	146 (18.2%)
31 - 35	39 (9.8%)	44 (11.0%)	83 (10.4%)
Median	23	22	22
Min, Max	18, 35	18, 35	18, 35



# Baseline Risk Behaviors by Treatment Group: Men (MITT cohort)

	Vaccine	Placebo	Total
Total Enrolled	222 (100.0%)	219 (100.0%)	441 (100.0%)
Circumcised			
Yes	61 (27.5%)	68 (31.1%)	129 (29.3%)
No	161 (72.5%)	151 (68.9%)	312 (70.7%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Number of Sexual Partners			
0	0 (0.0%)	0 (0.0%)	0 (0.0%)
1	90 (40.5%)	105 (47.9%)	195 (44.2%)
2	59 (26.6%)	46 (21.0%)	105 (23.8%)
3-4	55 (24.8%)	52 (23.7%)	107 (24.3%)
>=5	18 (8.1%)	16 (7.3%)	34 (7.7%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Median *	2	2	2
Min, Max	1, 20	1, 14	1, 20
Unprotected Vaginal/Anal Sex			
Yes	130 (58.6%)	126 (57.5%)	256 (58.0%)
No	92 (41.4%)	93 (42.5%)	185 (42.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unprotected Vaginal Sex *			
Yes	129 (58.1%)	125 (57.1%)	254 (57.6%)
No	93 (41.9%)	94 (42.9%)	187 (42.4%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unprotected Anal Sex w/ Female			
Yes	4 (1.8%)	7 (3.2%)	11 (2.5%)
No	218 (98.2%)	212 (96.8%)	430 (97.5%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unprotected Anal Sex w/ Male			
Yes	0 (0.0%)	1 (0.5%)	1 (0.2%)
No	222 (100.0%)	218 (>99%)	440 (>99%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unprotected Insertive Anal Sex w/ Male			
Yes	0 (0.0%)	1 (100.0%)	1 (100.0%)
No	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)



# Baseline Risk Behaviors by Treatment Group: Men (MITT cohort)

	Vaccine	Placebo	Total
Total Enrolled	222 (100.0%)	219 (100.0%)	441 (100.0%)
Unprotected Receptive Anal Sex w/ Male			
Yes	0 (0.0%)	1 (100.0%)	1 (100.0%)
No	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Had an HIV+ Partner			
Yes	4 (1.8%)	3 (1.4%)	7 (1.6%)
No	218 (98.2%)	216 (98.6%)	434 (98.4%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Exchange of Sex for Money/Gifts			
Yes	12 (5.4%)	12 (5.5%)	24 (5.4%)
No	210 (94.6%)	207 (94.5%)	417 (94.6%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Had a Casual/Anonymous Partner *			
Yes	109 (49.1%)	100 (45.7%)	209 (47.4%)
No	113 (50.9%)	119 (54.3%)	232 (52.6%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Drinking/Drugs with Sex *			
Yes	93 (41.9%)	81 (37.0%)	174 (39.5%)
No	129 (58.1%)	138 (63.0%)	267 (60.5%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diagnosed with a STI			
Yes	17 (7.7%)	10 (4.6%)	27 (6.1%)
No	205 (92.3%)	209 (95.4%)	414 (93.9%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Heavy Drinking <sup>1</sup> *			
Yes	49 (22.1%)	59 (26.9%)	108 (24.5%)
No	173 (77.9%)	159 (72.6%)	332 (75.3%)
Missing	0 (0.0%)	1 (0.5%)	1 (0.2%)



# Baseline Risk Behaviors by Treatment Group: Women (MITT Cohort)

	Vaccine	Placebo	Total
Total Enrolled	178 (100.0%)	182 (100.0%)	360 (100.0%)
Number of Sexual Partners			
0	0 (0.0%)	0 (0.0%)	0 (0.0%)
1	146 (82.0%)	158 (86.8%)	304 (84.4%)
2	29 (16.3%)	19 (10.4%)	48 (13.3%)
3-4	3 (1.7%)	5 (2.7%)	8 (2.2%)
>=5	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing *	0 (0.0%)	0 (0.0%)	0 (0.0%)
Median	1	1	1
Min, Max	1, 3	1, 3	1, 3
Unprotected Vaginal/Anal Sex			
Yes	102 (57.3%)	97 (53.3%)	199 (55.3%)
No	76 (42.7%)	85 (46.7%)	161 (44.7%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unprotected Vaginal Sex *			
Yes	101 (56.7%)	96 (52.7%)	197 (54.7%)
No	77 (43.3%)	86 (47.3%)	163 (45.3%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unprotected Anal Sex			
Yes	4 (2.2%)	5 (2.7%)	9 (2.5%)
No	174 (97.8%)	177 (97.3%)	351 (97.5%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Had an HIV+ Partner			
Yes	2 (1.1%)	1 (0.5%)	3 (0.8%)
No	176 (98.9%)	181 (99.5%)	357 (99.2%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Had a Main Partner >= 10 Years Older *			
Yes	14 (7.9%)	13 (7.1%)	27 (7.5%)
No	164 (92.1%)	169 (92.9%)	333 (92.5%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)



# Baseline Risk Behaviors by Treatment Group: Women

	Vaccine	Placebo	Total
Total Enrolled	178 (100.0%)	182 (100.0%)	360 (100.0%)
Had a Main Partner but Apart Regularly <sup>1</sup> *			
Yes	83 (46.6%)	74 (40.7%)	157 (43.6%)
No	95 (53.4%)	108 (59.3%)	203 (56.4%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Forced to Have Sex			
Yes	5 (2.8%)	2 (1.1%)	7 (1.9%)
No	173 (97.2%)	180 (98.9%)	353 (98.1%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Exchange of Sex for Money/Gifts			
Yes	2 (1.1%)	2 (1.1%)	4 (1.1%)
No	176 (98.9%)	180 (98.9%)	356 (98.9%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Had a Casual/Anonymous Partner *			
Yes	22 (12.4%)	18 (9.9%)	40 (11.1%)
No	156 (87.6%)	164 (90.1%)	320 (88.9%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Drinking/Drugs with Sex *			
Yes	26 (14.6%)	14 (7.7%)	40 (11.1%)
No	152 (85.4%)	168 (92.3%)	320 (88.9%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diagnosed with a STI			
Yes	10 (5.6%)	9 (4.9%)	19 (5.3%)
No	168 (94.4%)	173 (95.1%)	341 (94.7%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Heavy Drinking <sup>2</sup>			
Yes	7 (3.9%)	9 (4.9%)	16 (4.4%)
No	171 (96.1%)	173 (95.1%)	344 (95.6%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)

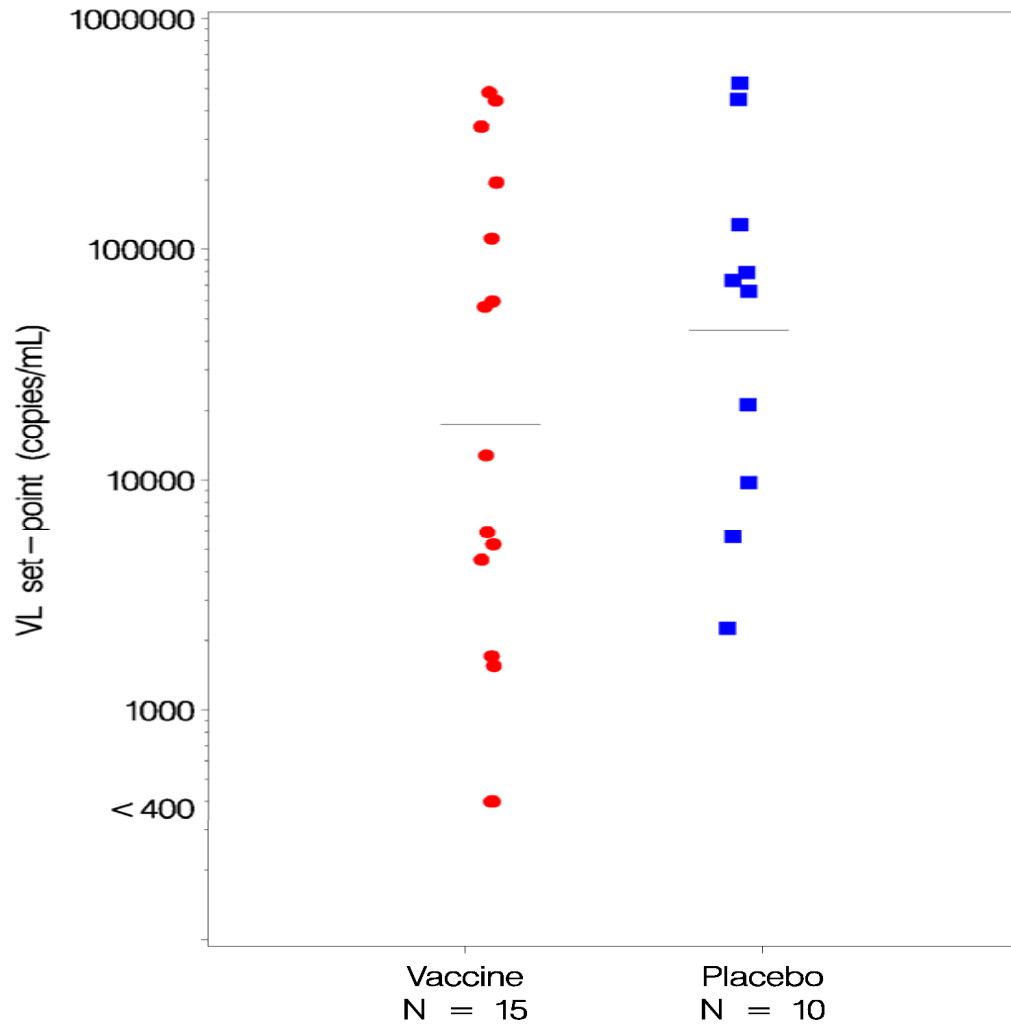


# HIV-1 endpoints by treatment group

	Vaccine	Placebo	Total
Infections in MITT Cohort	17	12	29
Site	-	-	-
Soweto-PHRU	7	3	10
Cape Town	6	4	10
KOSH	1	3	4
eThekweni	2	1	3
Medunsa	1	1	2
Adeno 05 Titer	-	-	-
<= 18	1	3	4
> 18	16	9	25
Gender	-	-	-
Male	4	3	7
Female	13	9	22
Adeno 05 Titer by Gender	-	-	-
<= 18 Male	0	1	1
<= 18 Female	1	2	3
> 18 Male	4	2	6
> 18 Female	12	7	19
Number Study Injections	-	-	-
1	6	1	7
2	10	11	21
3	1	0	1
Pre-treatment Notification	-	-	-
Yes	8	4	12
No	9	8	17
Baseline Circumcision Status (men only)	-	-	-
Yes	0	1	1
No	4	2	6
Infections in Per-protocol Cohort	9	9	18



# Viral Load Set-point by Treatment Arm



Geometric mean VL set-point

Vaccine 17,394 copies/mL

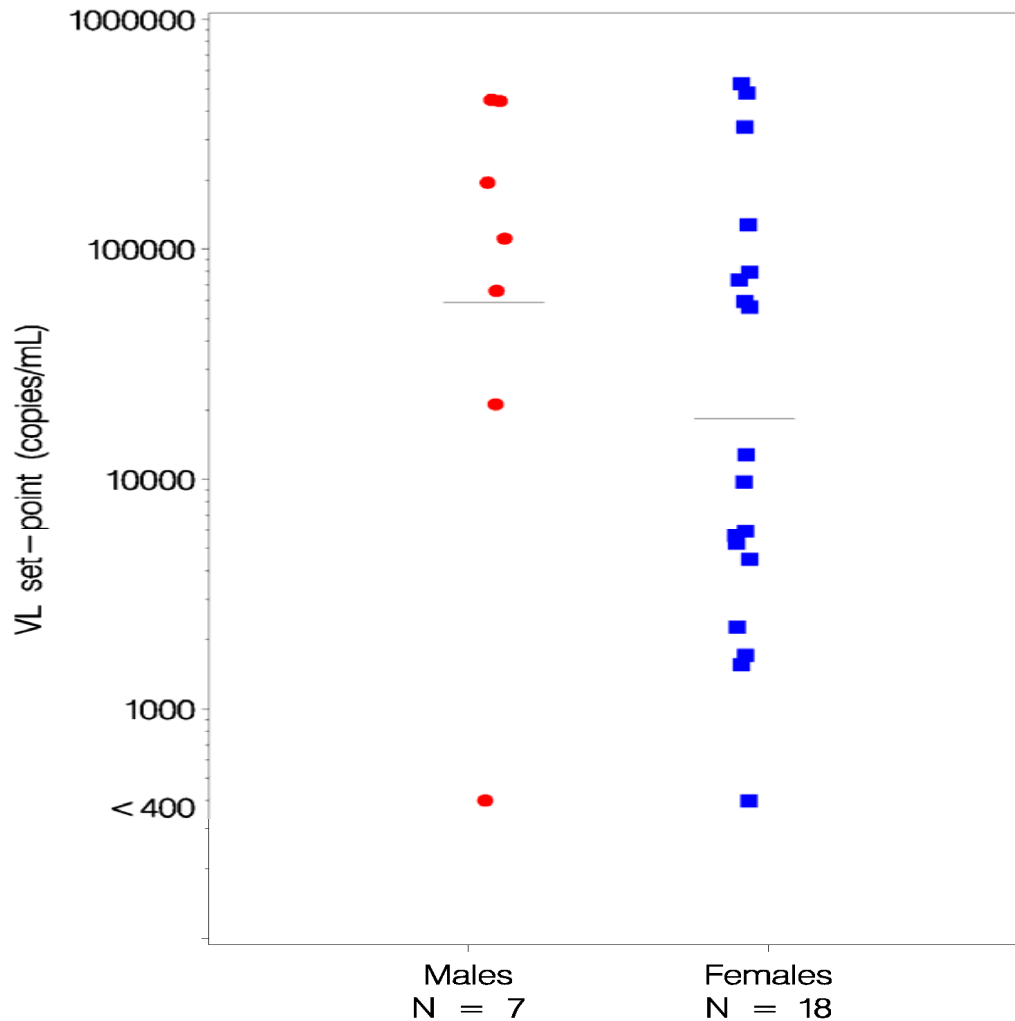
Placebo 44,611 copies/mL

Mean VL set-point

Vaccine 4.24 log<sub>10</sub> copies/mL

Placebo 4.65 log<sub>10</sub> copies/mL

# Viral Load Set-point by Gender



Geometric mean VL set-point

Males 58,699 copies/mL

Females 18,290 copies/mL

Mean VL set-point

Males 4.77 log<sub>10</sub> copies/mL

Females 4.26 log<sub>10</sub> copies/mL



# Baseline Risk Behaviors for HIV infected Men by Treatment Arm (MITT cohort)

	Vaccine	Placebo	Total
Total Enrolled	4 (100.0%)	3 (100.0%)	7 (100.0%)
Circumcised			
Yes	0 (0.0%)	1 (33.3%)	1 (14.3%)
No	4 (100.0%)	2 (66.7%)	6 (85.7%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Number of Sexual Partners			
0	0 (0.0%)	0 (0.0%)	0 (0.0%)
1	1 (25.0%)	1 (33.3%)	2 (28.6%)
2	1 (25.0%)	2 (66.7%)	3 (42.9%)
3-4	1 (25.0%)	0 (0.0%)	1 (14.3%)
>=5	1 (25.0%)	0 (0.0%)	1 (14.3%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Median	3	2	2
Min, Max *	1, 6	1, 2	1, 6
Unprotected Va			
Yes	3 (75.0%)	3 (100.0%)	6 (85.7%)
No	1 (25.0%)	0 (0.0%)	1 (14.3%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unprotected Vaginal Sex *			
Yes	3 (75.0%)	2 (66.7%)	5 (71.4%)
No	1 (25.0%)	1 (33.3%)	2 (28.6%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unprotected Anal Sex w/ Female			
Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)
No	4 (100.0%)	3 (100.0%)	7 (100.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unprotected Anal Sex w/ Male			
Yes	0 (0.0%)	1 (33.3%)	1 (14.3%)
No	4 (100.0%)	2 (66.7%)	6 (85.7%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unprotected Insertive Anal Sex w/ Male			
Yes	0 (0.0%)	1 (100.0%)	1 (100.0%)
No	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)



# Baseline Risk Behaviors for HIV infected Men by HIV treatment group (MITT cohort)

	Vaccine	Placebo	Total
Total Enrolled	4 (100.0%)	3 (100.0%)	7 (100.0%)
Unprotected Receptive Anal Sex w/ Male			
Yes	0 (0.0%)	1 (100.0%)	1 (100.0%)
No	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Had an HIV+ Partner			
Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)
No	4 (100.0%)	3 (100.0%)	7 (100.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Exchange of Sex for Money/Gifts			
Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)
No	4 (100.0%)	3 (100.0%)	7 (100.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Had a Casual/Anonymous Partner *			
Yes	3 (75.0%)	1 (33.3%)	4 (57.1%)
No	1 (25.0%)	2 (66.7%)	3 (42.9%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Drinking/Drugs with Sex *			
Yes	3 (75.0%)	2 (66.7%)	5 (71.4%)
No	1 (25.0%)	1 (33.3%)	2 (28.6%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diagnosed with a STI *			
Yes	1 (25.0%)	0 (0.0%)	1 (14.3%)
No	3 (75.0%)	3 (100.0%)	6 (85.7%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Heavy Drinking <sup>1</sup> *			
Yes	1 (25.0%)	1 (33.3%)	2 (28.6%)
No	3 (75.0%)	2 (66.7%)	5 (71.4%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)



## Baseline Risk Behaviors for HIV infected Women by treatment group (MITT cohort)

	Vaccine	Placebo	Total
Total Enrolled	13 (100.0%)	9 (100.0%)	22 (100.0%)
Number of Sexual Partners			
0	0 (0.0%)	0 (0.0%)	0 (0.0%)
1	9 (69.2%)	8 (88.9%)	17 (77.3%)
2	4 (30.8%)	1 (11.1%)	5 (22.7%)
3-4	0 (0.0%)	0 (0.0%)	0 (0.0%)
>=5	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Median	1	1	1
Min, Max	1, 2	1, 2	1, 2
Unprotected Vaginal/Anal Sex			
Yes	7 (53.8%)	3 (33.3%)	10 (45.5%)
No	6 (46.2%)	6 (66.7%)	12 (54.5%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unprotected Vaginal Sex *			
Yes	7 (53.8%)	3 (33.3%)	10 (45.5%)
No	6 (46.2%)	6 (66.7%)	12 (54.5%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unprotected Anal Sex			
Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)
No	13 (100.0%)	9 (100.0%)	22 (100.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Had an HIV+ Partner			
Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)
No	13 (100.0%)	9 (100.0%)	22 (100.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Had a Main Partner >= 10 Years Older *			
Yes	2 (15.4%)	0 (0.0%)	2 (9.1%)
No	11 (84.6%)	9 (100.0%)	20 (90.9%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)



# Baseline Risk Behaviors for HIV infected women by treatment group (MITT cohort)

	Vaccine	Placebo	Total
Total Enrolled	13 (100.0%)	9 (100.0%)	22 (100.0%)
Had a Main Partner but Apart Regularly <sup>1</sup> *			
Yes	5 (38.5%)	2 (22.2%)	7 (31.8%)
No	8 (61.5%)	7 (77.8%)	15 (68.2%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Forced to Have Sex *			
Yes	2 (15.4%)	0 (0.0%)	2 (9.1%)
No	11 (84.6%)	9 (100.0%)	20 (90.9%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Exchange of Sex for Money/Gifts			
Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)
No	13 (100.0%)	9 (100.0%)	22 (100.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Had a Casual/Anonymous Partner *			
Yes	3 (23.1%)	0 (0.0%)	3 (13.6%)
No	10 (76.9%)	9 (100.0%)	19 (86.4%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Drinking/Drugs with Sex			
Yes	1 (7.7%)	1 (11.1%)	2 (9.1%)
No	12 (92.3%)	8 (88.9%)	20 (90.9%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diagnosed with a STI			
Yes	1 (7.7%)	0 (0.0%)	1 (4.5%)
No	12 (92.3%)	9 (100.0%)	21 (95.5%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)
Heavy Drinking <sup>2</sup>			
Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)
No	13 (100.0%)	9 (100.0%)	22 (100.0%)
Missing	0 (0.0%)	0 (0.0%)	0 (0.0%)



HIV VACCINE  
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## Conclusions

- Vaccination did not impact on HIV infection
- Data on viral load set-point is emerging
- Formal interim analysis is planned on 30 HIV infections once data on the viral load is available (expected January 2009)

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